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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/705,398	11/10/2003	Shutsung Liao	10634-002002 / UCHI 751	4394
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BOSTON, MA 02110				
EXAMINER				
BADIO, BARBARA P				
ART UNIT		PAPER NUMBER		
1616				

DATE MAILED: 01/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/705,398

Applicant(s)

LIAO ET AL.

Examiner

Barbara P. Badio, Ph.D.

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-66 is/are pending in the application.
- 4a) Of the above claim(s) 1-17, 23-27, 30, 33 and 35-64 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 18-22, 28, 29, 31, 32, 34, 65 and 66 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 11/03; 11/04; 9/04.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☒ Other: IDS 8/04.

**First Office Action on the Merits**

***Election/Restrictions***

1. Applicant's election without traverse of compound #30 found on page 10 of the present specification in the reply filed on November 3, 2004 is acknowledged.

2. Based on applicant's elected species, the following generic group will be examined in the present application:

Compounds as defined by claim 18 wherein:

n is 0;

X is alkyl or alkenyl;

Y is a bond; and

Z is alkyl, alkenyl, alkynyl, cycloalkyl, heterocycloalkyl, cycloalkenyl, heterocycloalkenyl, aryl, heteroaryl, aralkyl or heteroaralkyl and is optionally substituted with hydroxy, alkoxy, amino, halo, sulfonic acid, -O-sulfonic acid, carboxyl, oxo, alkyloxycarbonyl, alkylcarbonyloxy, alkylaminocarbonyl, alkylcarbonylamino, alkylcarbonyl, alkylsulfinyl, alkylsulfonyl or alkylthio.

Note: The above-mentioned group will be examined according to MPEP § 803.02.

3. Based on above-mentioned group and the elected compound, claims 1-17, 23-27, 30, 33 and 35-64 stand withdrawn as being drawn to a nonelected species. Claims

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18-22, 28, 29, 31, 32, 34, 65 and 66 will be examined to the extent they read on the elected species and obvious variants thereof.

### ***Specification***

4. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

### ***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 34 and 66 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The instant claims are indefinite because they lack a period. Therefore, the skilled artisan would be unable to determine the metes and bound of the instant claims.

### ***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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8. Claims 18-22, 28, 29, 31, 32 and 65 are rejected under 35 U.S.C. 102(b) as being anticipated by Kihira et al.

Kihira et al. teach several analogs of bile acids such as 23-iodo-24-nor-5 $\beta$ -cholane-3 $\alpha$ ,6 $\alpha$ -diol and 24-iodo-5 $\beta$ -cholane-3 $\alpha$ ,6 $\alpha$ -diol and ethanolic compositions thereof (see the entire article, especially page 195, compounds 4e and 4h). The compounds and compositions taught by the reference are encompassed by the instant claims.

9. Claims 18-22, 28, 29, 31, 32 and 65 are rejected under 35 U.S.C. 102(b) as being anticipated by Huang et al.

Huang et al. teach the production of fluorine-containing steroids such as 20-(8-chloro-3,3,4,4,5,5,6,6-octafluorohexyl)-5 $\beta$ -pregnane-3 $\alpha$ ,6 $\alpha$ -diol and 20-(6-chloro-3,3,4,4,5,5,6,6,7,7,8,8-dodecafluorooctyl)-5 $\beta$ -pregnane-3 $\alpha$ ,6 $\alpha$ -diol (see the entire article, especially page 307 and 313, compounds 4a-4e). The compounds and compositions taught by the reference are encompassed by the instant claims.

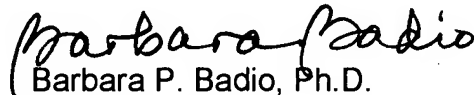
### ***Telephone Inquiry***

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio, Ph.D. whose telephone number is 571-272-0609. The examiner can normally be reached on M-F from 6:30am-4:00pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary L. Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Barbara P. Badio, Ph.D.  
Primary Examiner  
Art Unit 1616

BB  
January 19, 2005